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Director

Memorandum

To: **Senate Judiciary I Subcommittee on Pharmaceutical Liability**
From: **Kelly Quick, Research Assistant**
Date: **April 24, 2012**
Re: **Summary of April 2012 Report of the FDA Center for Drug Evaluation and Research on Its Post-Marketing Monitoring Activities**

This memorandum summarizes a report released on April 21, 2012, by the FDA Center for Drug Evaluation and Research (CDER), detailing its Post-Marketing Monitoring Activities.[1]

FDA's Center for Drug Evaluation and Research (CDER)'s role is to ensure drug safety through premarket review and postmarket monitoring. In this report, FDA describes the actions CDER has taken to enhance the quality, accountability, and timeliness of its postmarket drug safety decisions.

Food and Drug Administration Amendments Act (FDAAA)

- Food and Drug Administration Amendments Act (FDAAA) was enacted in 2007, which greatly revised laws governing Agency responsibilities and gave FDA new authorities in drug safety.
- Most significant safety provisions under FDAAA and the status of their implementation:
    - Postmarket studies and clinical trials
        - FDAAA granted FDA the authority to require manufacturers to conduct postmarket safety studies and clinical trials at the time of or after the approval of a drug. Prior to FDAAA, these studies were conducted as voluntary commitments by manufacturers. Since 2008, FDA has required more than 385 postmarket drug safety studies.
    - Required labeling changes:
        - FDAAA granted authority to FDA to require a change in a drug's label to include new safety information. Prior to FDAAA, the Agency did not have authority to order such label changes if the company did not voluntarily make the change. Since 2008, FDA has required new safety labeling 65 tunes using its FDAAA authority, generally for whole classes of drugs (e.g., providing safety information on the adverse effects on newborns of antipsychotic drugs taken during pregnancy).
    - Risk Evaluation and Mitigation Strategies (REMS) authorities:
        - Under FDAAA, the Agency can require manufacturers to implement special risk management programs, called risk evaluation and mitigation strategies (REMS), for their products if FDA believes such a program is necessary to assure that the drug's benefits outweigh the risks. Since 2008, FDA has required 64 REMS programs.
    - Quarterly online reports
        - In accordance with FDAAA, FDA posts two types of online reports and summaries related to adverse event reports.

[1] To download this 30 page report, go to http://www.fda.gov/downloads/Drugs/DrugSafety/UCM300946.pdf. A shorter, "Drug Safety Highlights" brochure is available at http://www.fda.gov/downloads/Drugs/DrugSafety/UCM300944.pdf.

        - Reports listing any potential signals of serious risks or new safety information that were identified using the Adverse Event Reporting System (AERS) database.
        - Summary information about ongoing and completed postmarket safety evaluations of adverse experience reports made to FDA for New Drug Applications and Biologic License Applications. The evaluations determine if there are any new serious adverse events not previously identified during product development, known side effects reported in unusual numbers, or potential new safety concerns.
- FDA has made advances in four major areas to execute FDAAA provisions:
    - Safety First
    - Safe Use
    - Strengthening drug safety science
    - Drug Safety Communications

<u>Safety First</u>

- Safety First is a series of internal initiatives to ensure that FDA gives the same priority to the oversight of the safety of marketed drugs as it does to premarket safety review.
- Objectives include:
    - Prioritizing postmarket safety issues according to their degree of risk to patient safety
    - Enhancing the quality and timeliness of specific drug safety decisions so that FDA responds quickly and appropriately to emerging safety issues
    - Ensuring that drug safety decisions are made collaboratively, using a team model that considers all relevant scientific viewpoints
    - Implementing the drug safety authorities and responsibilities authorized by Congress in FDAAA

<u>Safe Use</u>

- In 2009, FDA launched the Safe Use Initiative to reduce preventable drug harm caused by inappropriate use, such as intentional overdose or inappropriate prescribing.

<u>Strengthening Drug Safety Science</u>

- The Sentinel Initiative: A long-term program to create a national electronic system for securely accessing health care data to monitor the safety of drugs and other FDA-regulated medical products.
- FDA's Mini-Sentinel pilot program, a large-scale working model of the eventual full-scale sentinel system, enables FDA to assess medical product safety issues by utilizing access to the electronic health care information of more than 125 million patients.
- FDA has made strides in advancing the evaluation of potential risks into the development of new drugs, so that risks are identified early and risk management strategies are considered when FDA is deciding whether to approve a drug.

<u>Drug Safety Communications</u>

- FDA has created a systematic approach to providing the public with information about possible new drug risks and how FDA is addressing them.
- The changes include:
    - Having a single format for communicating drug safety issues, called a Drug Safety Communication (DSC), as opposed to the multiple formats used in the past
    - Undertaking studies of the most effective methods of communicating drug safety issues
    - Publishing articles in medical journals to explain the evidence and analyses used by FDA to make its benefit-risk assessments for specific drugs
    - Seeking advice from its internal Drug Safety Oversight Board